REMARKS

The office action dated June 9, 2009 (the "Office Action") has been received and carefully noted. Claims 1, 3-20 and 26-32 were examined. Claims 1, 3-18, 26 and 31 were rejected. Applicant notes with appreciation that claims 19, 20, 27-30 and 32 are objected to as allowable if rewritten in independent form. Applicant amends claims 1, 11, 27-28; and submits additional claim 33. Applicant submits that no new matter is added therein as part of claim 27 is incorporated into claim 1; part of claim 28 is incorporated into claim 11; and additional claim 33 is prior claim 11 and portions of claims 14 and 19. Hence, Applicants have amended independent claims 1 and 11; and submitted additional claim 33 to include what Applicant believes are the allowable limitations from claims 27-28 and 19 which are indicated as allowable in the current Office Action.

Hence, Applicant respectfully requests reconsideration of claims 1, 3-18 26 and 31 as amended; and consideration of additional claim 33 in view of at least the following remarks.

I. Claims Rejected Under 35 U.S.C. § 103

A.

Claims 1, 3, 5-9, 11, 14-18 and 26 were rejected under 35 U.S.C. § 103 (a) as being unpatentable over in view of U.S. Patent No. 6,063,085 to Tay et al. ("*Tay*"), in view of U.S. Patent No. 6,539,792 to Lull, et al. ("*Lull*"). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicants respectfully submit that a *prima facie case* of obviousness has not been established.

More particularly, none of the cited references either singly or combined provide the suggestion or motivation to modify the references. The mere fact that the references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP 2143.01. Independent claim 1 is directed to a thermally conducted heating element coupled to the distal portion of the needle, wherein the heating element is coupled to balanced circuit which measures a first differential resistance between the heating element and a variable resistor in response to a first condition and second

differential resistance in response to a second condition to indicate a change of conditions related to a distance of penetration of the heating element into a tissue from a fluid boundary with the tissue, wherein the first condition comprises the distal portion of the needle penetrating a vessel wall first location and disposed in fluid, and the second condition comprises the distal portion of the needle extending through the fluid and disposed within tissue of a vessel wall second location. Independent claim 11 is directed to a needle coupled to a thermally conductive heating element at a portion of the needle adjacent to the distal end of the needle; and a interface to electrically couple an anemometry circuitry to the heating element, wherein the circuitry comprises a balanced circuit having a heating element and a variable resistor to measure a first and second resistance in response to a first and a second condition, wherein the first condition comprises the distal end of the needle disposed in fluid, and the second condition comprises the distal portion of the needle disposed in the fluid and the distal end disposed within tissue.

According to the Application, a balanced circuit is capable of measuring heat dissipation characteristics of a tissue environment in which the heating element is disposed. Thus, independent claims 1 and 11 contemplate an apparatus for determining injection depth from a fluid boundary with the tissue by measuring a first resistance when the distal portion of the needle penetrates a vessel wall first location and is disposed in fluid, and measuring a second resistance when the distal portion of the needle extends through the fluid and is disposed within tissue of a vessel wall second location; and/or tissue type at a distal end of a needle based on the heat dissipation characteristics of body tissue using a thermally conductive heating element: (1) coupled to a distal portion of the needle (claim 1), or (2) coupled to a portion of the needle adjacent to the distal end (claim 11). (App., p.2, Ins. 9-11)

In contrast, *Tay* discloses an apparatus for closing and sealing a puncture at a puncture site in a vessel located beneath the skin using radio frequency or other energy to cauterize the puncture. (col. 2, Ins. 45-47) *Tay* only teaches a distal end of the needle within fluid of a punctured vessel (see FIGs. 26-30). *Lull* discloses a sensor that includes a first resistor, a second resistor, a first circuit, and a second circuit wherein the first and second resistors each has a resistance that varies in response to a change in a physical property. (Abstract) According to *Lull*, the sensor can be applied in semiconductor manufacturing processes and automotive applications. (col. 17. Ins. 1-5)

However, neither of the references teaches the heating element coupled to the distal portion, or coupled adjacent the distal end of the needle to by measuring a first resistance when the distal portion of the needle penetrates a vessel wall first location and is disposed in fluid, and measuring a second resistance when the distal portion of the needle extends through the fluid and is disposed within tissue of a vessel wall second location as required by claims 1 and 11.

In addition, the Patent Office states that it would have been obvious to position the heating element on the distal portion of the needle disclosed by *Tay* to avoid creating an additional unnecessary puncture. However, this position does not make sense as *Tay* teaches using the device tip to cauterize and repair a pre-existing puncture (col. 2, Ins. 45-47); and only teaches a needle going through a pre-existing puncture of a damaged vessel, and extending into fluid within the vessel (see FIGs. 26-32) but does not teach penetration or puncturing a tissue from a fluid boundary with the tissue, as required by amended claim 1.

Moreover, the principle purpose of *Tay* is to close and seal pre-existing punctures of a vessel. Thus *Tay* does not teach, but teaches against a needle for puncturing a vessel (see column 2, lines 45-47); or having a sharpened end (see claim 12).

In addition, by coupling the heating element to the distal portion of the needle (see claim 1), or to a portion of the needle adjacent to the distal end (see claim 11), embodiments described in the specification, for example, without limitation thereto, provide benefits of: (1) allowing accurate determination of an injection depth from a fluid boundary with the tissue; and/or tissue type to inject drugs into blood filled cavities without visually guiding a needle of an injection device or having some other indication of the needle location within a patients body (see page 1, lines 12-20; page 2, lines 8-19; and page 3, line 31- page 4, line 15); (2) such as to allow the heating element to be disposed distal to an injection opening to more accurately determine injection depth of a distal portion or end of a needle that penetrates the vessel wall, extends through fluid, and is disposed within tissue of another location of the vessel wall, such as in cases where a larger signal/reading is obtained when the tip of the needle has entered tissue just distal to the desired injection depth (see page 6, lines 1-13; claims 27 and 28; and additional claims 31-32); (3) allowing multiple heating elements to be mounted on the needle to select more accurate measurement between multiple penetration depths and tissue types based on a selection of heating elements to be operated (see page 9, lines 1-7; page 16, lines 32 through page 17, line 32 and FIG. 7; and new claims 20 and 29); and/or (4) allowing for more accurate control of a depth

of penetration of a sharpened needle into the wall of a coronary artery to a desired penetration depth (see page 15, line 15 through page 16, line 31; FIG. 6; and claim 12). However, none of the cited references teach or enable such benefits.

Moreover, there is no suggestion in the cited references that it is desirable to combine a sensor which, according to *Lull*, can be used in semiconductor manufacturing processes and automotive applications with a vessel cauterizing medical device, as taught by *Tay*. The statement made by the Examiner that it would have been obvious to modify *Tay* in view of *Lull* "in order to compare variations in the resistance of the heating element" is merely a characteristic of the sensor described in *Lull* and is not a proper motivation to combine the cited references. (Office Action, p.4-5)

Moreover, the fact that a claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. MPEP 2143.01. In response to Applicant's previous arguments that a proper motivation to combine was not set forth, the Examiner states: "Tay et al. fails to disclose any specific circuitry to control the anemometer. As a result, one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer." (Office Action, p.6) The Examiner has provided no objective reason to combine *Tay* with *Lull*, but has merely made a generic statement that "one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer." The Examiner has not met his burden in providing a proper motivation to combine the cited references.

Furthermore, Applicant asserts that the Examiner has improperly combined the references because *Tay* teaches away from the claims. MPEP 2145(X)(D). A prior art reference must be considered in its entirety including portions that lead away from the claimed invention. MPEP 2141.02(VI). Independent claim 1 includes the limitation of "a needle having . . . a distal portion suitable for ***insertion*** into tissue . . . and a lumen extending from a proximal end to the distal opening and in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening." Independent claim 11 includes the limitation of "a needle having dimensions suitable for insertion into a body, and having a distal end capable of ***puncturing*** skin." Thus, the needle in Applicant's invention is either inserted into or punctures skin. By contrast, the cautery apparatus in *Tay* is designed to seal an already existing puncture wound in a vessel. (col. 5, Ins. 10-62) Representatively, *Tay* discloses that the "present invention

effects the hemostatic closure of a percutaneous or other type of puncture, incision or opening in a body vessel." (col. 5, Ins. 45-57) Thus, *Tay* teaches away from independent claims 1 and 11 and therefore was improperly combined with *Lull*.

B.

Claims 4 and 13 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 3,740,604 to Zenick ("*Zenick*"). Dependent claim 4 depends from dependent claim 2 which depends from independent claim 1. Dependent claim 13 depends from independent claim 11. Therefore, claims 4 and 13 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

C.

Claims 10 and 18 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 5,873,835 to Hastings et al. ("*Hastings*"). Dependent claim 10 depends from independent claim 1. Dependent claim 18 depends from dependent claim 14 which depends from independent claim 11. Therefore, claims 10 and 18 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

D.

Claim 12 is rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 6,110,183 to Cope ("*Cope*"). Dependent claim 12 depends from independent claim 11. Therefore, claim 12 includes at least each and every limitation of claim 11. Thus, in view of the remarks above, independent claim 11 and dependent claim 12 are patentably allowable.

In addition to being dependent upon allowable base claim 11, Applicants disagree with the rejection of dependent claim 12 for at least the reason that the cited references do not teach the needle of claim 11 having an outer diameter between 0.009 and 0.134 inches, and having a sharpened distal end, as required by amended claim 12. As noted above, the primary purpose of *Tay* is to use a device having a rounded end to repair a pre-existing puncture of a vessel (see FIGs. 26-32); but does not teach the above noted limitations of claim 12.

Tay teaches the purpose and principle of operation of a needle going through a pre-existing puncture of a damaged vessel and extending into fluid within the vessel (see Figs. 26-33) but does not teach penetrating tissue or a vessel using a needle with a sharpened distal end, as required by claim 12. The purpose of *Tay* is to cauterize or repair pre-existing punctures of a vessel (see column 2, lines 45-47). Thus upon reading *Tay* a practitioner would not consider using a needle to puncture a vessel using a sharpened distal end of the needle. In the **Response to Arguments** section of the current Office Action (see page 6, lines 17-19), the Patent Office states that a rigid object having a diameter as disclosed by *Tay* is capable of puncturing skin, depending on the amount of force applied. Applicants point out that the same logic applies to any object. However, the point is that such use of the device of *Tay* is against the primary purpose and principle of operation of *Tay* (see MPEP 2143.01 (V and VI)). Consequently, *Tay* cannot be properly combined with *Cope* to teach the above noted limitations of claim 12.

II. Allowable Claims 19, 20, 27-30 and 32

Applicants note with appreciation that the Patent Office has indicated that claims 19, 20, 27-30 and 32 are allowable if rewritten in independent form. Applicants have incorporated portions of these claims into independent claims in an attempt to construct allowable independent claims.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending are now in condition for allowance and such action is earnestly solicited at the earliest possible date. If there are any additional fees due in connection with the filing of this response, please charge those fees to our Deposit Account No. 02-2666. Questions regarding this matter should be directed to the undersigned at (310) 207-3800.

Respectfully submitted,

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Dated: 2009-08-14

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